K092585

OCT 3 0 2009

510(k) Summary

Introduction

According to the requirements of 21 CFR 807.92, the following information provides sufficient detail to understand the basis for a determination of substantial equivalence.

Submitter name, address, contact

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Date Prepared: August 21, 2009

Device Name

Proprietary name: Elecsys Rubella IgG CalCheck 5
Common name: Rubella IgG CalCheck 5
Classification name: Single (specified) analyte controls (assayed and unassayed)

Predicate device

The Elecsys Rubella IgG CalCheck 5 is substantially equivalent to other products in commercial distribution intended for similar use. We claim equivalency to the currently marketed Elecsys Rubella IgG CalCheck (K090311).

Device Description

The Elecsys Rubella IgG CalCheck 5 is a lyophilized product consisting of human anti-Rubella IgG antibodies in human serum matrix. During manufacture, the analyte is spiked into the matrix at the desired concentration levels.

Intended use

The Elecsys Rubella IgG CalCheck 5 is an assayed control for use in calibration verification and for use in the verification of the assay range established by the Elecsys Rubella IgG reagent on the Elecsys 2010, MODULAR ANALYTICS E170 and **cobas e** immunoassay analyzers.

Comparison Table

The table below compares Elecsys Rubella IgG CalCheck 5 with the predicate device, Elecsys Rubella IgG Calcheck (K090311).

Characteristic	Elecsys Rubella IgG CalCheck (K090311)	Elecsys Rubella IgG CalCheck 5
Intended Use	The Elecsys Rubella IgG CalCheck is an assayed calibrator control intended for use in the verification of the calibration established by the Elecsys Rubella IgG reagent on the Elecsys 2010, MODULAR ANALYTICS E170 and **cobas e** immunoassay analyzers.	The Elecsys Rubella IgG CalCheck 5 is an assayed control for use in calibration verification and for use in the verification of the assay range established by the Elecsys Rubella IgG reagent on the Elecsys 2010, MODULAR ANALYTICS E170 and **cobas e** immunoassay analyzers.
Levels	Three	Five
Format	Lyophilized	Same
Handling	Reconstitute with exactly 1.0 mL distilled or deionized water and allow standing closed for 15 minutes, then mix gently by inversion.	Same
Stability	Unopened: • Store at 2-8°C until expiration date Reconstituted: • 20 – 25°C : 4 hrs	Same
Matrix	Human serum matrix	Same

Performance Characteristics

The Elecsys Rubella IgG CalCheck 5 was evaluated for value assignment and stability.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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OCT 3 0 2009

Re: K092585

Trade/Device Name:	Elecsys Rubella IgG CalCheck 5
Regulation Number:	21CFR §862.1660 21CFR §866.3510
Regulation Name:	Quality Control Material (assayed and unassayed) Rubella Virus Serological Reagents
Regulatory Class:	Class I (Quality Control) Class II (Rubella IgG)
Product Code:	JJX, LFX
Dated:	August 21, 2009
Received:	August 24, 2009

Dear Ms. French:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Sally A. Hojvat, M.Sc ., Ph.D.
Director
Division of Microbiology Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indication for Use

510(k) Number (if known): k092585

Device Name: Elecsys Rubella IgG CalCheck 5

Indication For Use:

The Elecsys Rubella IgG CalCheck 5 is an assayed control for use in calibration verification and for use in the verification of the assay range established by the Elecsys Rubella IgG reagent on the Elecsys 2010, MODULAR ANALYTICS E170 and **cobas e** immunoassay analyzers.

Prescription Use __X____ And/Or Over the Counter Use ____.
(21 CFR Part 801 Subpart D) (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Uwe Scherf

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) k092585